

balance for best health, endurance, and longer life. This ideal calcium balance is easily accomplished and maintained by the use of SOLTAN CALCIUM WATER \* \* \*"

The article was also alleged to be adulterated and misbranded under the provisions of the law applicable to drugs, as reported in notices of judgment on drugs and devices.

DISPOSITION: June 16, 1945. No claimant having appeared, judgment was entered ordering that the product and the booklets be destroyed.

**7918. Misbranding of Walker's Mineralized Vitamin Tablets. U. S. v. 14 Boxes and 2 Boxes of Mineralized Vitamin Tablets. Default decree of condemnation and destruction. (F. D. C. No. 13118. Sample No. 81993-F.)**

LIBEL FILED: August 2, 1944, District of New Jersey.

ALLEGED SHIPMENT: On or about June 1, 1944, by Walker Vitamin Products, Inc., from Mount Vernon, N. Y.

PRODUCT: 14 boxes, each containing 50 tablets, and 2 boxes, each containing 250 tablets, of Walker's Mineralized Vitamin Tablets, at Jersey City, N. J.

Tests showed that these tablets passed through the gastro-intestinal tract without disintegration.

LABEL, IN PART: "Walker's Mineralized Vitamin Tablets."

VIOLATIONS CHARGED: Misbranding, Section 403(a), the following label statements were false and misleading: "Mineralized Vitamin Tablets Contains Fat-Free Fish Liver Oil Concentrate, Synthetic Vitamins and Mineral Salts to Supply In Each Tablet Vitamin A (Natural) 5000 Int. Units Vitamin B<sub>1</sub> (Thiamine) 3.0 Mg. Vitamin B<sub>2</sub> (Riboflavin) 2.0 Mg. Vitamin B<sub>6</sub> (Pyridoxine) .1 Mg. Calcium Pantothenate 1.0 Mg. Niacinamide 20.0 Mg. Vitamin C (Ascorbic Acid) 30.0 Mg. Vitamin D (Viosterol) 500 Int. Units Iron—15 Mg., Calcium—50 Mg., Phosphorus—40 Mg., Magnesium, Manganese and Zinc—Each ½ Mg. Each tablet supplies the adult daily minimum requirement of Iron and Vitamins A, B<sub>2</sub>, C, D and three times this requirement of Vitamin B<sub>1</sub>, plus 20 mg. of Niacinamide,—also approximately 7% of the calcium and phosphorus requirements. The need for pyridoxine and calcium pantothenate in human nutrition has not been established,—nor has the need for dietary supplementation with magnesium, manganese and zinc been determined. Dose: One or two tablets daily as a dietary supplement." The product, when taken as directed, passed through the human body without disintegration, and therefore did not make available to the body the vitamins and minerals contained in the tablets.

DISPOSITION: March 26, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**7919. Adulteration and misbranding of Watkins Vitamins A B D G Tablets, and misbranding of Watkins Cod Liver Extract Tablets. U. S. v. The J. R. Watkins Co. Plea of nolo contendere. Fine, \$60. (F. D. C. No. 11432. Sample Nos. 38808-F, 38809-F.)**

INFORMATION FILED: January 23, 1945, District of Minnesota, against the J. R. Watkins Co., a corporation, Winona, Minn.

ALLEGED SHIPMENT: During the month of April 1943, from the State of Minnesota into the State of Illinois.

PRODUCT: Analysis of the Watkins Cod Liver Extract Tablets disclosed that they contained 3,465 U. S. P. units of vitamin A and 314 U. S. P. units of vitamin D per tablet. In addition, the article was represented to contain 1 grain of dicalcium phosphate per tablet.

Analysis of the Watkins Vitamins A B D G Tablets disclosed that they contained not more than 225 U. S. P. units of vitamin A, not more than 100 U. S. P. units of vitamin D, and approximately 0.375 milligram or 125 units of vitamin B<sub>1</sub> (thiamine chloride) per tablet.

VIOLATIONS CHARGED: Watkins Cod Liver Extract Tablets, misbranding, Section 403 (a), because of misleading statements in an accompanying circular which represented and implied that defective bone and tooth formation, poor health and improper growth, lack of resistance to common cold symptoms and similar minor infections of the respiratory tract, poor appetite, lowered resistance to infections, dry skin, lack of vigor, diarrhea, digestive disturbances, cessation of growth, physical weakness, formation of kidney and gall stones, catarrh, sinusitis, ear abscesses, restlessness, bowlegs, potbelly, constipation, infantile tetany, convulsions, enlarged joints, softened bones, pigeon breast,

curvature of the spine, and retarded growth and marked depletion of calcium and phosphorus in the body commonly and usually result from lack of the vitamins and mineral contained in the article; that the user might reasonably expect that the consumption of the article would correct such conditions; that vitamins A and D are usually lacking in the ordinary diet; and that it is necessary for all persons to supplement the diet each day with additional amounts of vitamins A and D. The conditions referred to in the labeling commonly and usually result from causes other than lack of the vitamins and mineral in the article; the user might not reasonably expect that consumption of the article would bring about correction of such conditions, since it would not ordinarily be efficacious for such purposes; and vitamins A and D are usually supplied by the ordinary diet in adequate amounts, and, consequently, most persons do not need additional amounts thereof. Further misbranding, Section 403 (j), the article purported to be and was represented as a food for special dietary uses by man by reason of its content of vitamin A and vitamin D, and by reason of its mineral content of phosphorus, but its label did not bear, as required by the regulations, a statement of the proportion of the minimum daily requirements of vitamin A, vitamin D, and phosphorus which would be supplied by the article when consumed in a specified quantity during a period of 1 day.

Watkins Vitamins ABDG Tablets, adulteration, Section 402 (b) (1), valuable constituents of the article, vitamins A, B<sub>1</sub>, and D, had been in whole or in part omitted or abstracted therefrom, since the article was represented to contain in each tablet 2,000 U. S. P. units of vitamin A, 200 U. S. P. units of vitamin D, and ½ milligram or 167 units of vitamin B<sub>1</sub>, whereas it contained per tablet not more than 225 U. S. P. units of vitamin A, not more than 100 U. S. P. units of vitamin D, and not more than 0.375 milligram of vitamin B<sub>1</sub>, equivalent to 125 units of vitamin B<sub>1</sub>.

Misbranding, Section 403 (a), the label statements, "Vitamins A-B-D-G Tablets Each Tablet contains: 2,000 U. S. P. Units Vitamin A; 200 U. S. P. Units Vitamin D (Viosterol); 1-2 Milligram or 167 Units Vitamin B<sub>1</sub> (Thiamin Chloride); \* \* \* Watkins Vitamins ABDG Tablets are biologically and chemically assayed for measured doses," and similar statements appearing in an accompanying circular, were false and misleading.

Further misbranding, Section 403 (a), because of misleading statements on its label and in an accompanying leaflet which represented and implied that vitamins A, B, D, and G are usually lacking in the ordinary diet; that it is necessary that the diet of babies, children, and adults be supplemented regularly with additional amounts of these vitamins; that supplemental vitamins need be consumed even though there may be no lack of the vitamins in the diet; that low resistance to infections, lack of normal growth, poor appetite, dry skin, lowered resistance to certain types of infection, lack of vigor, diarrhea, digestive disturbances, poor growth, injury to the nerve tissues, neuritis, polyneuritis, loss of appetite, unhealthy skin and mucous membranes, and lack of normal motor, sensory, and central nervous system functions are usually caused by lack of the vitamins contained in the article; and that the user might reasonably expect that the consumption of the article would correct such conditions. Vitamins A, B, D, and G are not usually lacking in the ordinary diet, but are usually present in adequate amounts; it is not necessary that the diet of babies, children, and adults be supplemented regularly with additional amounts of the vitamins; supplemental vitamins need not be consumed unless there is a lack of the vitamins in the diet; and the conditions referred to in the labeling commonly and usually result from causes other than lack of vitamins, and would not ordinarily be corrected by use of the article.

Further misbranding, Section 403 (j), the article purported to be and was represented as a food for special dietary uses by man by reason of its content of vitamins A, B<sub>1</sub>, D, and G (B<sub>2</sub>), and its label did not bear, as required by the regulations, a statement of the proportions of the minimum daily requirements for vitamins A, B<sub>1</sub>, D, and G (B<sub>2</sub>) which would be supplied by the article when consumed in a specified quantity during a period of 1 day.

The articles were also alleged to be misbranded, and the vitamin tablets were also alleged to be adulterated, under the provisions of the law applicable to drugs, as reported in the notices of judgment on drugs and devices.

DISPOSITION: January 23, 1945. A plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$10 on each of 6 counts, a total fine of \$60.